IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
AT CLARKSBURG

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS CORPORATION, NOVARTIS AG, AND NOVARTIS PHARMA AG,,	)	Civil Action No. 1:14-cv-111-IMK
Plaintiffs,	)	
v.	)	
MYLAN PHARMACEUTICALS INC. and Mylan Inc.,	)	
Defendants.	)	

MYLAN PHARMACEUTICALS INC.'S AND MYLAN INC.'S MOTION TO COMPEL PRODUCTION OF ALL PRIOR LITIGATION DOCUMENTS

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Dated: March 30, 2015

I. INTRODUCTION

Pursuant to Federal Rules of Civil Procedure Rule 26 (b) (1) and 33, Defendants Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, "Mylan") respectfully seek the Court's assistance in compelling Plaintiffs to produce all of the documents from *Novartis Pharm. Corp., et al. v. Actavis, Inc., et al.*, C.A. No. 12-00366-RGA-CJB (D. Del. dismissed Apr. 29, 2014) ("Prior Litigation") which Novartis is withholding based on the fact that it contains Actavis Inc. ("Actavis") Confidential material. The requests at issue include at least request numbers 15, 16, 24 and 62 in Mylan's first set of requests to Plaintiffs.[1] Mylan understands Plaintiffs' position to be that: they will not produce certain documents from the Prior Litigation designated by Actavis as "confidential" pursuant to the protective order in that case, absent Actavis's consent. The Delaware protective order explicitly states that "by entering this order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case." Dkt. 36 ¶ 29 in Case 1:12-cv-00366-RGA-CJB attached as Exhibit A.

With this motion, Mylan seeks to provide Actavis with its "opportunity to appear and be heard" regarding any issues related to the confidentiality of its information produced, disclosed, or relied upon in the Prior Litigation and to ensure all parties that it will treat any material produced in this litigation in accordance with the operative protective order. Along with this motion to compel Mylan also respectfully requests the Court to establish a deadline of no later than April 10th for Actavis to intervene if it chooses to be heard. Mylan understands all parties to agree that Actavis should be allowed to intervene with regard to this limited issue, and both parties have put Actavis on notice that Mylan is seeking the documents held by Novartis. Actavis has been aware of Mylan's request at least as early as February 23, 2015and has refused consent of production despite Mylan's agreement to adhere to the terms of the protective order.

[1] The responses of Plaintiffs, which re-iterates the requests themselves, are attached hereto as Exhibit C.

II. BACKGROUND

This is a patent infringement case relating to Mylan Pharmaceuticals' filing of Abbreviated New Drug Application ("ANDA") No. 206585, seeking approval to market a generic deferasirox drug product. Plaintiffs Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG, and Novartis Corporation (collectively, "Plaintiffs") have alleged that Mylan's ANDA product will infringe Plaintiffs' patents—U.S. Patent No. 6,465,504 (the '504 patent) and U.S. Patent No. 6,596,750 (the '750 patent) (collectively, "the asserted patents"). In addition to owning the asserted patents, Plaintiffs hold the new drug application ("NDA") for deferasirox drug products (marked as EXJADE®), which are "indicated for the treatment of chronically elevated levels of iron in the blood caused by repeated blood transfusions." The '504 patent is generally directed to a compound or composition including deferasirox, and the '750 patent is generally directed to a method of treating certain diseases by administering deferasirox.

The asserted patents have already been litigated close to trial against Actavis in the Prior Litigation. Similar to the instant case, the Prior Litigation was a patent infringement case relating to Actavis' filing of an ANDA seeking approval to market a generic deferasirox product. For these asserted patents, the infringement inquiries revolve around the deferasirox drug compound and the proposed product label of the generic manufacturer. Although the product label is considered confidential prior to the launch of a pharmaceutical product, Federal law requires the ANDA applicant's product label to generally conform to at least a portion of the brand product's label. Thus in the current matter, although the Actavis label is technically confidential, the contents of the label are reasonably ascertainable given the publicly available Novartis brand label. Thus the infringement considerations in the Prior Litigation and the present litigation are practically certain to overlap.

The parties failed to resolve their disputes in multiple discussions, including a final telephonic meet-and-confer at 2:00 p.m. on March 11, 2015.[2]

[2] The counsel involved were Gordon Copland, Sami Sedghani and Nicole Stafford (for Mylan) and James Companion, Kevin Prussia and Kelli Powell (for Novartis).

III. ARGUMENT

A. The Prior Litigation Documents Are Both Relevant and Probative on Critical Issues Being Litigated in This Case

The documents Mylan seeks are undeniably relevant to Mylan's claims for invalidity and non-infringement as well as to issues related to claim construction. In the Prior Litigation, both Actavis and Novartis produced documents and expert reports related to issues of invalidity as well as non-infringement of the proposed ANDA product for generic EXJADE®. Because of the extreme similarity of the invalidity and non-infringement issues between the Prior Litigation and this case [e.g.: (i) each suit is an ANDA litigation concerning the reference listed drug EXJADE®; (ii) Novartis is the plaintiff in each suit; (iii) each suit concerns at least the invalidity and non-infringement of the same patents; and (iv) Novartis will likely retain the same experts from the prior case], and the fact that the material was produced pursuant to a virtually identical protective order, there is no reason to preclude the production of documents containing incidental Actavis confidential information.

The specific categories of documents that relate to similar issues in this case generally include: (i) all discovery responses; (ii) all expert depositions and expert reports; and (iii) the identification of any testing or prior art. In addition to the relevance of these documents, unilateral access to Novartis provides an unfair advantage to Plaintiffs and potentially allows their experts to take positions that would be inconsistent with the positions taken in the Prior Litigation. Furthermore, to the extent that Novartis uses the same experts for infringement, Mylan is entitled to discover all the facts the expert previously considered and relied on. See FED. R. CIV. P. 26(a)(2)(B) (requiring disclosure of, e.g.: (i) all of the facts or data considered by the expert.).

Thus, it is evident that the withheld documents which include for example: discovery responses, expert depositions, and expert reports from the Prior Litigation are relevant to this litigation, and that Novartis's experts should not be permitted to take contradictory positions

from the Prior Litigation. Both Mylan and this Court have a right to full discovery of Novartis's positions taken in the prior case, as well as evidence produced with regard to issues related to infringement, invalidity, and claim construction.

Furthermore, Novartis has advocated for the adoption of the same construction of patent claim terms as that before the Delaware Court in the Prior Litigation. Mylan submits that it would violate all notions of fundamental fairness that a party be forced to defend against an action or take positions as to the claim construction order from the Prior Litigation without access to the full underlying record. It is thus critical for Mylan to have access to the discovery from the Prior Litigation to investigate whether the constructions posed were not motivated by one party's litigation concerns.

As for Prior Litigation documents that relate purely to sensitive Actavis business information, to the extent any exist, Mylan is amenable to stipulating to treat these documents as "Outside Counsel Eyes Only." Thus Mylan's request is narrowly tailored to obtain the most relevant information while balancing third party confidentiality concerns.

B. There Are Adequate Safeguards In This Case To Protect The Confidential Material

The risk of competitive injury resulting from the disclosure of Actavis' commercially-sensitive information is minimal. The protective order in the current case was modeled on the Delaware protective order from the Prior Litigation (which Actavis was a party to) and strikes the appropriate balance between a party's need for access to another person's confidential information against the risks and consequences of disclosure of such information. The protective order in this case prohibits dissemination of confidential material to Mylan's business employees and prohibits the use of "confidential material" beyond the present litigation. Furthermore, access to confidential material is limited solely to Mylan's outside counsel, three previously designated in-house counsel, and designated independent experts. Dkt. 51 (Protective Order) attached as Exhibit B.

Fed. R. Civ. P. 26(c) places the burden of establishing "good cause" for protecting confidential information squarely on the party seeking protection. Courts have been clear that the fact that Actavis and Mylan may be competitors does not provide a reason for Novartis to withhold production of relevant material to Mylan. *See, e.g., Opperman v. Allstate N.J. Ins. Co.* , No. 07-1887, 2008 WL 5071044, at *4 (D.N.J. Nov. 24, 2008) (compelling party to produce third party' confidential information); *Sedona Corp. v. Open Solutions., Inc*., 249 F.R.D. 19, 24-25 (D. Conn.) (same); *JAB Distribs., LLC v. London Luxury*, LLC, No. 09-5831, 2010 WL 4008193, at *1, *3-*4 (N.D. Ill. Oct. 13, 2010) (same); *In re Wellbutrin XL Antitrust Litig*., No. 08-2431, slip op. at 1, 4-7 (E.D. Pa. Nov. 10, 2009) (D.I. 128) (compelling production, noting that "the Court believes that its proposal reaches the fairest outcome when the interests of all sides in this matter are considered and adequately protects [the generic company's] sensitive information"). Since Mylan is bound by the terms of the protective order, any confidential information will be adequately protected. Thus there is no appreciable risk that any sensitive information could be used to gain a competitive advantage.

Furthermore, Mylan is represented by outside counsel with extensive experience in multi Defendant Hatch Waxman cases and is routinely provided access to competitor Defendants confidential information, further minimizing the risks of improper use or dissemination. Other than Mylan's outside counsel, any person—including Mylan's own in-house counsel—who seeks access to confidential documents will need to sign the agreement to be bound by the protective order and provide the producing party an opportunity to object for good cause.

C. Plaintiffs Tactic to Delay the Production of Prior Litigation Documents Will Unfairly Prejudice Mylan

Mylan understands that Actavis has the right, under the protective order to assure protection of its confidential information as would Mylan appreciate the same courtesy if the situation was reversed. Mylan should not be required to sit in the dark and wait for Novartis to

produce a log of these pertinent documents only to have to be faced with the same objection from Actavis.

Mylan needs the complete expert reports and discovery responses from the prior litigation to prepare its defenses with regard to invalidity and infringement. Thus, absent intervention from Actavis by April 10th, Novartis should be compelled to provide "all" prior litigation documents currently withheld forthwith. It is preferable that this issue be resolved now so that all concerned, including Actavis, know that disclosure of their confidential information to Mylan is treated with the same safeguards as was present when they produced the information to Novartis.

IV. CONCLUSION

For the foregoing reasons, Mylan respectfully requests the Court to grant Mylan's motion to compel the production of Prior Litigation documents, including but not limited to all submissions to the Court (including pleadings, letters, motions, briefs, declarations and exhibits), all responses to written discovery requests concerning validity or infringement of the patents, all expert reports and declarations (including exhibits thereto), and any other documents produced in response to a request for production that relates to the issue of invalidity or infringement of the asserted patents.

Respectfully submitted on March 30, 2015.

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Certification Under Fed. R. Civ. P. 37

The undersigned counsel certifies that Mylan conferred with counsel for Novartis in a good faith effort to resolve the disputes without resort to involvement of the Court.

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CERTIFICATE OF SERVICE

I hereby certify that on March 30, 2015, I electronically filed the foregoing "Mylan Pharmaceuticals Inc.'s And Mylan Inc.'s Motion To Compel Production Of All Prior Litigation Documents" with the clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to the following counsel of record:

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